containing the abrasive calcium pyrophosphate.

(2) *Preventive treatment gel.* Stannous fluoride 0.4 percent in an anhydrous glycerin gel, made from anhydrous glycerin and the addition of suitable thickening agents to adjust viscosity.

(3) *Treatment rinse.* Stannous fluoride concentrate marketed in a stable form and containing adequate directions for mixing with water immediately before using to result in a 0.1-percent aqueous solution.

[60 FR 52507, Oct. 6, 1995, as amended at 61 FR 52286, Oct. 7, 1996]

§ 355.20 Packaging conditions.

(a) *Package size limitation.* Due to the toxicity associated with fluoride active ingredients, the following package size limitations are required for anticaries drug products:

(1) *Dentifrices.* Dentifrice (toothpastes and tooth powders) packages shall not contain more than 276 milligrams (mg) total fluorine per package.

(2) *Preventive treatment gels and treatment rinses.* Preventive treatment gel and treatment rinse packages shall not contain more than 120 mg total fluorine per package.

(3) *Exception.* Package size limitations do not apply to anticaries drug products marketed for professional office use only and labeled in accord with § 355.60.

(b) *Tight container packaging.* To minimize moisture contamination, all fluoride powdered dentifrices shall be packaged in a tight container as defined as a container that protects the contents from contamination by extraneous liquids, solids, or vapors, from loss of the article, and from efflorescence, deliquescence, or evaporation under the ordinary or customary conditions of handling, shipment, storage, and distribution, and is capable of tight reclosure.

Subpart C—Labeling

§ 355.50 Labeling of anticaries drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as: (select one or both of the following: 'anticavity' or 'fluoride') (select one of the following as appropriate: ''dentifrice,'' ''toothpaste,'' ''tooth polish,'' ''tooth powder;'' (optional: ''dental'') ''preventive treatment gel;'' or (optional: ''treatment'' or ''dental'')) (select one of the following: ''rinse,'' ''concentrated solution,'' ''rinse powder,'' or ''rinse effervescent tablets''). The word ''mouthwash'' may be substituted for the word ''rinse'' in this statement of identity if the product also has a cosmetic use, as defined in section 201(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(i)).

(b) *Indication.* The labeling of the product states, under the heading ''Indication,'' the following: ''Aids in the prevention of dental (select one of the following: ''cavities,'' ''decay,'' ''caries (decay),'' or ''caries (cavities)''). Other truthful and nonmisleading statements, describing only the indication for use that has been established and listed in this paragraph (b), may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) *Warning.* The labeling of the product contains the following warning under the heading ''Warning'':

(1) *For all fluoride dentifrice (gel, paste, and powder) products.* ''Keep out of the reach of children under 6 years of age. If you accidentally swallow more than used for brushing, seek professional assistance or contact a Poison Control Center immediately.'' These warnings shall be used in place of the general warning statements required by § 330.1(g) of this chapter.

(2) *For all fluoride rinse and preventive treatment gel products.* ''Keep this and all drugs out of the reach of children. If you accidentally swallow more than used for'' (select appropriate word: ''brushing'' or ''rinsing''), ''seek professional assistance or contact a Poison Control Center immediately.'' These warnings shall be used in place of the general warning statements required by § 330.1(g) of this chapter.